REMARKS

Procedural History

Applicants canceled Claims 1-18 (directed to anti-idiotypic antibodies and related subject matter) and added Claims 19-56 (directed to methods of treating TNF-mediated blood pathology) in the Preliminary Amendment filed on July 5, 2002. A copy of the filed Preliminary Amendment and a copy of the stamped postcard indicating a receipt date of July 10, 2002 by the United States Patent and Trademark Office are enclosed as evidence that the Preliminary Amendment was filed and received by the United States Patent and Trademark Office.

Applicants canceled Claims 23, 48 and 49 in the Second Preliminary Amendment filed on October 3, 2002. A copy of the filed Second Preliminary Amendment and a copy of the stamped postcard indicating a receipt date of October 7, 2002 by the United States Patent and Trademark Office are enclosed as evidence that the Second Preliminary Amendment was filed and received by the United States Patent and Trademark Office.

The Office Action mailed from the United States Patent and Trademark Office on July 7, 2004 states that Claims 1-18 are pending, and that Claims 5-7 and 13 are allowed. Therefore, it appears that the Preliminary Amendment filed on July 5, 2002, and the Second Preliminary Amendment filed on October 3, 2002, were not acknowledged by the Examiner.

Examiner Interview

Applicants thank the Examiner for her telephone call on August 31, 2004 to discuss the procedural issues regarding the pending Office Action and the filed Preliminary Amendments. Applicants also thank the Examiner for her helpful suggestions for responding to the Office Action.

Title of the Invention

Applicants have amended the title to be clearly indicative of the invention. No new matter has been added by this amendment. Therefore, entry of this amendment into the application is respectfully requested.

Claim Amendments

In this Amendment, Applicants have now canceled all pending claims and added Claims 57-65.

Claims 57-60 correspond to originally-filed Claims 5-7 and 13, which the pending Office Action indicates are allowable. Claim 57 is directed to an anti-idiotypic antibody, or functional fragment thereof, which is specific for cA2. Support for this new claim is found, for example, in the specification at page 17, lines 21-27 and in the originally-filed Claim 5. Claim 58 is directed to an anti-idiotypic antibody of Claim 57 which binds to one or more CDRs of cA2 or A2. Support for this new claim is found, for example, in the specification at page 19, lines 9-19; page 20, lines 15-25; page 26, lines 28-31; and in the originally-filed Claim 6. Claim 59 is directed to an anti-idiotypic antibody of Claim 57 which is murine. Support for this new claim is found, for example, in the specification at page 19, lines 9-19; page 21, lines 1-3; and in the originally-filed Claim 7. Claim 60 is directed to an anti-idiotypic antibody containing at least one antigen recognition site which mimics antigenic regions of human TNF-α, said anti-idiotypic antibody obtained from a hybridoma produced by fusing mouse splenocytes immunized with A2 or cA2 with myeloma cells. Support for this new claim is found, for example, in the specification at page 19, lines 9-19; page 25, line 36 to page 26, line 19; and in the originally-filed Claim 13.

Claims 61-65 are directed to immunoassay methods for detecting an anti-TNF-α antibody. Claim 61 relates to similar subject matter as Claim 17, and is directed to an immunoassay method for detecting an anti-TNF-α antibody in a sample comprising contacting said sample with an anti-idiotypic antibody to an anti-TNF-α antibody, wherein the anti-TNF-α antibody comprises an amino acid sequence selected from the group consisting of SEQ ID NO:3 and SEQ ID NO:5, in detectably labeled form; and detecting the binding of the anti-idiotypic antibody to the anti-TNF-α antibody, wherein the anti-TNF-α antibody is detected. Claims 62-65 are directed to immunoassay methods for detecting an anti-TNF-α antibody in a sample, comprising contacting said sample with the anti-idiotypic antibody of Claims 57-60, respectively, in detectably labeled form, and detecting the binding of the anti-idiotypic antibody to the anti-TNF-α antibody, wherein the anti-TNF-α antibody is detected. Support for these new claims is found, for example, in the specification at page 19, lines 9-19; page 69, line 30 to page 70, line 3; page 12, lines 19-24; Figure 17B; and in the originally-filed Claims 5-7 and 17.

No new matter has been added by the amendments. Therefore, entry of the amendments into the application is respectfully requested.

Information Disclosure Statement

Applicants respectfully request that the related application section of the Information Disclosure Statement (IDS) filed on September 13, 2002 be acknowledged by the Examiner.

Priority Date

The Examiner states that Claims 1-13 and 17 are given an effective priority date of January 29, 1993, commensurate in scope with U.S. Serial No: 08/010,406, and Claims 14-16 and 18 are given an effective priority date of July 2, 2001, the filing date of the instant patent application.

Applicants respectfully disagree. Applicants have canceled Claims 1-18. Applicants have added new Claims 57-61 which correspond to Claims 5-7, 13 and 17, respectively. New Claims 57-61 are entitled to priority to U.S. Application Serial No. 07/670,827 (the '827 application), filed March 18, 1991, for example, because the '827 application discloses anti-idiotypic antibodies. Claims 57-61 are fully supported by the '827 application. See, for example, page 38, line 18 to page 39, line 4 of the '827 application.

Applicants have added new Claims 62-65 which are directed to an immunoassay method for detecting an anti-TNF-α antibody in a sample. New Claims 62-65 are entitled to priority to U.S. Application Serial No. 07/670,827 (the '827 application), filed March 18, 1991, for example, because the '827 application discloses anti-idiotypic antibodies. Claims 62-65 are fully supported by the '827 application. See, for example, page 38, line 18 to page 39, line 4 of the '827 application.

This priority application has been properly referenced on page 1 of the specification in compliance with 35 U.S.C. § 120.

Rejection of Claims 1-3, 8-12, 17 and 18 under 35 U.S.C. § 112, second paragraph

Claims 1-3, 8-12, 17 and 18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. With regard to Claim 17, according to the Examiner:

> The antecedent basis of "antibody" in section b of [claim] 17... is unclear as [the claim recites] two different antibodies in section a of the method. Further, it is unclear if the "antibody to an antibody" as recited in claim 17...encompass antibodies which bind to the antibody and antiidiotypic antibody isotype in addition to the idiotype.

The Examiner further states that "Claim 17 lacks a method step which relates the binding to the antibody to TNF with the method objective of detecting an anti-TNF antibody in a sample."

Applicants have canceled Claims 1-3, 8-12 and 17-18. New Claim 61 has been added, which are similar in scope to Claim 17. New Claim 61 has been drafted to address the Examiner's rejections to Claim 17.

New Claim 61 recites antecedent basis for "antibody" in section (b). The language of Claim 61 makes clear that Applicants are claiming an anti-idiotypic antibody to an anti-TNF-α antibody. Further, Claim 61 recites a method step which relates the binding of the anti-idiotypic antibody to the anti-TNF-α antibody, wherein the anti-TNF-α antibody is detected. In sum, all of the 35 U.S.C. § 112 rejections for Claim 17 has been addressed in new Claim 61.

Rejection of Claims 1, 2 and 12 under 35 U.S.C. § 102(a)

Claims 1, 2 and 12 are rejected under 35 U.S.C. § 102(a) as being anticipated by Galloway, *et al.* or Barbanti, *et al.*

Applicants have canceled Claims 1, 2 and 12. Therefore, the rejection is moot.

Rejection of Claim 17 under 35 U.S.C. § 102(b)

Claim 17 is rejected under 35 U.S.C. § 102(b) as being anticipated by Moller, *et al.* According to the Examiner, the anti-mouse IgG of Moller "...fulfills the specific embodiment of an antibody to an antibody comprising amino acid sequence selected from the group consisting of

SEQ ID NO: 3 and 5 because the claim does not state that the antibody must be an anti-idiotypic antibody versus and anti-isotypic antibody."

Applicants have canceled Claim 17. New Claim 61 has been added which is similar in scope to Claim 17. New Claim 61 recites that the antibody in the claim is an anti-idiotypic antibody.

Moller discloses reacting anti-mouse IgG with a sample comprising antibodies bound to TNF-α. Moller does not teach an anti-idiotypic antibody. Therefore, Moller does not anticipate Claim 61.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of Claims 1, 2, 4, 11 and 12 under 35 U.S.C. § 103(a)

Claims 1, 2, 4, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbanti, *et al.* in view of Moller, *et al.*

Applicants have canceled Claims 1, 2, 4, 11 and 12. Therefore, the rejection to Claims 1, 2, 4, 11 and 12 is moot.

Rejection of Claims 14 and 18 under 35 U.S.C. § 103(a)

Claims 14 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Moller *et al.* in view of Lee *et al.*

Applicants have canceled Claims 14 and 18. Therefore, the rejection of Claims 14 and 18 is moot.

Rejection of Claims 14-16 and 18 under 35 U.S.C. § 103(a)

Claims 14-16 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Le, *et al.* in view of Lee *et al.*

Applicants have canceled Claims 14-16 and 18. Therefore, the rejection of Claims 14-16 and 18 is moot.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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PROPOSED AMENDMENT

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